

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant	Andersen, et al.
Application No. 10/529,137	Filing Date: September 6, 2005
Title of Application:	Low Moisture Chewing Gum
Confirmation No. 2575	Art Unit: 1794
Examiner:	Corbin, Arthur L

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is in support of Applicant's Notice of Appeal filed on February 5, 2009.

APPEAL BRIEF

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I. Real Party in Interest

The real party in interest for the present application is Gumlink A/S. Gumlink A/S is the assignee of record of the present application per an assignment recorded, on September 6, 2005, by inventors Lone Andersen and Helle Wittorff.

II. Related Appeals and Interferences

To the best of the Applicant's knowledge, there are no appeals or interferences which are directly related to the present appeal.

III. Status of Claims

Claims 1-55 were originally filed in the present application. Claims 2 and 8 have been cancelled. Claims 1, 3-7, and 9-55 are currently pending, are the subject of the present appeal and are set forth in the Appendix (section VIII) to this appeal brief.

IV. Status of Amendments

In response to the final rejection of this application, an amendment was submitted on December 4, 2008. Subsequently, in an Advisory Action, dated December 17, 2008, the Examiner stated that the proposed amendments would be entered. The claims defined in that Amendment are set forth in the Claims Appendix.

V. Summary of the Claimed Subject Matter

Claim 1 is the only rejected independent claim and is discussed below.

Independent Claim 1

In general terms, the applicants' disclosure relates to a technology wherein relatively small amounts of water in a chewing gum containing biodegradable polymers affects the degradation of the chewing gum even before chewing has occurred, making small amounts of water or moisture within such a chewing gum highly desired (see page 1, lines 18-23).

Moisture in chewing gum is typically provided by different water containing chewing gum ingredients such as sweeteners. One type of sweetener is carbohydrate syrups, such as conventional corn syrups or sugar alcohol syrups (including sorbitol solutions and hydrogenated starch hydrolysate solutions) typically added to chewing gum compositions to improve binding and softness characteristics in the gum. (see page 1, lines 25-29)

A problem of a low moisture chewing gum is that a lower water content results in a less attractive texture of the chewing gum. Therefore, additional softeners typically need to be added. This is a problem, however, when dealing with a biodegradable chewing gum, since a chewing gum made on the basis of a biodegradable polymer has turned out to be more vulnerable to softeners than chewing gum made on the basis of conventional polymers. (see page 2, lines 1-8)

Surprisingly, it has now been discovered that chewing gum made on the basis of biodegradable polymers, most probably due to the hydrophilic nature of typical biodegradable polymers, exhibits a significantly faster gaining of softness during the initial chew compared to chewing gum made on the basis of conventional hydrophobic polymers. (see page 2, lines 10-14)

Based upon several experiments under different conditions, a chewing gum made on the basis of biodegradable polymers having an initial stiffness (the very first chew) greater than conventional chewing gum, actually increases in softness much faster than conventional chewing gum, thereby reaching the initial acceptable texture before the conventional chewing gum. It has moreover been realized that this phenomena is also present when almost no moisture is present in the chewing gum as from the beginning. (see page 2, lines 16-22)

According to the present invention, as embodied in Claim 1, a biodegradable chewing gum having low moisture content is provided wherein a low moisture content is obtained in combination with an initial acceptable texture. More specifically, independent Claim 1 requires a chewing gum comprising at least one biodegradable polymer and chewing gum ingredients, wherein said chewing gum ingredients are selected from the group consisting of softeners, sweeteners, flavoring agents, active ingredients, fillers, and mixtures thereof, and wherein said chewing gum contains from about 0.01 to about 2.0 weight percent water of the chewing gum. (see page 2, lines 24-26; page 2, lines 31-32, page 3, lines 20-21; page 4, lines 29-30; page 5, lines 23-24; page 6, line 11; page 6, lines 23-24; page 8, line 29)

For the grouping of the claims, Applicant suggests the following groupings:

Group I: Claims 1-39 and 49-55

Group II: Claims 40-48

Group I is directed towards a chewing gum comprising at least one biodegradable polymer and chewing gum ingredients which are selected from the group consisting of

softeners, sweeteners, flavoring agents, active ingredients, fillers, and mixtures thereof. The chewing gum contains from about 0.01 to about 2.0 weight percent water by weight of the chewing gum. The at least one biodegradable polymer is a polyester polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters is selected from the group consisting of glycolides, lactides, lactones, cyclic carbonates and mixtures thereof. Additionally, the chewing gum is substantially free of water containing sweeteners or softeners.

Group II is directed towards a biodegradable polymer-based chewing gum having a water content of about 0.01 to about 2.0 weight percent water by weight of the chewing gum and the chewing gum is coated with a hard outer coating. The chewing gum may also have additional ingredients which are selected from the group consisting of softeners, sweeteners, flavoring agents, active ingredients, fillers, and mixtures thereof. The hard outer coating is selected from the group consisting of a sugar coating and a sugarless coating and a combination thereof.

VI. Grounds of Rejection to be Reviewed on Appeal

- A) Whether claims 1-39 and 49-55 are unpatentable under 35 U.S.C. §103(a) over Grijpma et al. (US 5,672,367, cols. 1-3).
- B) Whether claims 40-48 are unpatentable under 35 U.S.C. §103(a) over Grijpma et al. (US 5,672,367, cols. 1-3), and further in view of Meyers (US 5,433,960 cols. 3 and 9-13 and claims 1, 16, 27).
- C) Whether claims 1-30, 32-42, 46, 47 and 49-55 are unpatentable under 35 U.S.C. §103(a) over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42).
- D) Whether claim 31 is unpatentable under 35 U.S.C. §103(a) over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42) and further in view of Grijpma et al. (col. 3, line 4) or Li et al (US 6,153,231, col. 7, lines 60-61).
- E) Whether claims 43-45 and 48 are unpatentable under 35 U.S.C. §103(a) over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42) and further in view of Meyers (US 5,433,960 cols. 3 and 9-13 and claims 1, 16, 27).

VII. Arguments

An invention is not patentable “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”¹ For a claim to be rejected as obvious, the Office is required to determine the scope and content of the prior art, ascertain the differences between the claimed invention and the prior art, and resolve the level of ordinary skill in the art.² This analysis must be set forth explicitly.³ When considering the prior art, the office is required to consider the prior art as a whole, and may not disregard portions of the art which show that an invention is not obvious.⁴ Additionally, it is important to guard against the use of hindsight when evaluating whether a claim is obvious.⁵ As a guard against hindsight, courts have identified certain scenarios in which it is improper to reject a claim as obvious. For example, a claim cannot properly be rejected as obvious when the principle of operation of the prior art would need to be modified to obtain the claimed invention.⁶ Similarly, if a prior art reference teaches away from a claimed invention, then the claimed invention is not obvious over that prior art.⁷ Given these standards, the Office’s rejections under 35 U.S.C. § 103(a) cannot be sustained and must be reversed for the reasons set forth below.

¹ 35 U.S.C. § 103(a).

² *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007); MPEP § 2141, citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

³ *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

⁴ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).

⁵ E.g., *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”).

⁶ *In re Ratti*, 270 F.2d 810 (CCPA 1959) (cited in MPEP 2143.01 for the proposition that “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”).

- A. Claims 1-39 and 49-55 are not properly rejected under 35 U.S.C. §103(a) as obvious in view of Grijpma et al. (US 5,672,367, cols. 1-3).

The rejections of the above-referenced claims are improper because Grijpma et al. does not teach, motivate or suggest to one skilled in the art that a low moisture-content chewing gum would be desirable. In making this rejection, the examiner relies on the false premise that finding the optimum amount of water and flavoring agents to include in the chewing gum, based upon Grijpma et al., would require nothing more than routine experimentation by one reasonably skilled in the art.

Grijpma et al. is directed to biodegradable chewing gum comprising one or more conventional chewing gum components and a gum base having at least one biodegradable polymer selected from the group of polyesters and polycarbonates. Nowhere in Grijpma et al. is the moisture/water content range of the chewing gum addressed. Grijpma et al. is silent as to this aspect of biodegradable chewing gum design. Rather, the moisture/water content in the Grijpma et al. chewing gum is collateral in that moisture content is inherent in the chewing gum ingredients - softeners, including glycerin, hydrogenated starch hydrolysate, sorbitol and cane sugar syrup (col. 2, lines 48-52). Water content however is never explicitly mentioned. For instance, hydrogenated starch hydrolysate will typically contain about 25% w/w of water, and sorbitol (liquid form) contains about 15% w/w water. Thus, water is inherently contained in the Grijpma et al. chewing gum, simply through the use of certain standard ingredients, which already have a *relatively high water content and much higher than the claimed 2% or less level in the pending application.*

⁷ See MPEP § 2145 citing *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983).

Further, there are no teachings in Grijpma et al. regarding an acceptable range for water content in a biodegradable chewing gum. Contrary to a misstatement made in the May 21, 2008 response, for which misstatement Applicants apologize, the Applicants want to emphasize that it is *not* well-known to those skilled in the art that high water content in chewing gum comprising biodegradable polymers may cause a degradation problem such that the biodegradable polymers of the chewing gum may be hydrolytically degraded prior to chewing as a result of too much water being present inside the chewing gum.

According to the present invention high water content in chewing gum comprising biodegradable polymers may cause a pre-degradation problem, meaning that the biodegradable polymers of the chewing gum may be hydrolytically degraded prior to chewing as a result of too much water being present inside the chewing gum. The problem with a low moisture content chewing gum is that it has a less attractive texture and hence additional softeners are needed. The presence of additional softeners (and hence water) in a biodegradable chewing gum makes the biodegradable polymer more vulnerable (page 2, lines 5-8 of pending application).

A review of Grijpma et al. provide no guidance to one skilled in the art as to how much water is needed for a biodegradable chewing gum to have the desired and comparable texture of a non-biodegradable gum and also how to avoid potential premature degradation of the product. Grijpma et al. does not deal expressly with water content of the gum at all. Rather, Grijpma et al. only teaches that softeners should account for up to 15% by weight of the chewing gum (col. 2, line 48), even though it is well-known in the art that softeners such as liquid sorbitol, glycerine, and sugar syrup generally contain high percentages of water. Accordingly, one skilled in the art reading Grijpma et al. would conclude that, given the inherent amount of water

contained in the ingredients of the chewing gum, that high water content is necessary in order to achieve a biodegradable chewing gum with the desired texture of a non-biodegradable gum.

Therefore, because the rejections of claim 1-39 and 49-55 rely on the incorrect premise that Grijpma et al. teaches one skilled the art that a biodegradable chewing gum having a water content from about 0.01 to about 2.0 weight percent would provide the same desired textural qualities of a traditional, non-biodegradable chewing gum, the rejection of claims 1-39 and 49-55 should be reversed, and those claims should be allowed in their current form.

B. Claims 40-48 are improperly rejected under 35 U.S.C. §103(a) as obvious over Grijpma et al. (US 5,672,367, cols. 1-3), and further in view of Meyers (US 5,433,960 cols. 3 and 9-13 and claims 1, 16, 27).

Applicants submit that the art of record fails to teach, suggest or motivate one skilled in the art to coat the chewing gum in Grijpma et al. with a coating as claimed by the Applicant in claims 40-48 in order to provide storage stability to the low-moisture biodegradable chewing gum.

As with Grijpma et al., also Meyers provides no guidance to one skilled in the art as to how much water is needed for a biodegradable chewing gum to have the desired and comparable texture of a non-biodegradable gum and also how to avoid potential premature degradation of the product. Therefore, the teaching of Grijpma et al. in further view of Meyers do not teach, suggest or motivate one skilled in the art to have a biodegradable chewing gum with a water content of from about 0.01 to about 2.0 weight percent and still expect that it possess the same desired texture qualities of a traditional, non-biodegradable chewing gum.

For at least these reasons, the rejection of claims 40-48 under 35 U.S.C. §103(a) should be reversed and claims 40-48 should be allowed in their current form.

C. Claims 1-30, 32-42, 46, 47 and 49-55 are improperly rejected under 35 U.S.C. §103(a) as obvious over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42).

The Examiner's rejection of claims 1-30, 32-42, 46, 47 and 49-55 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. is flawed.

Goldberg et al. discloses a chewing gum including one or more biodegradable polymers, conventional chewing gum ingredients and coated with a coating syrup. The Examiner states that finding the optimum amount of water and flavoring agents would require nothing more than routine experimentation by one reasonably skilled in the art.

A review of Goldberg et al. provides no guidance to one skilled in the art as to how much water is needed for a biodegradable chewing gum to have the desired and comparable texture of a non-biodegradable gum and also how to avoid potential premature degradation of the product. Goldberg et al. is directed to improved gum bases comprising condensation copolymers which are polymerized from a first monomer which is capable of polymerization by condensation polymerization, e.g., ring opening lactone polymerization, and a second monomer which is effective to suppress the crystallization of the copolymer. Goldberg et al. teaches that the copolymers can provide enhanced properties in gum bases comprising the copolymers.

Contrary to an erroneous statement in the 21 May 2008 response Goldberg et al. does not disclose a specific water content of the chewing gum. Goldberg et al. discloses and claims (claim 15) that water uptake of the disclosed co-polymers is advantageous. Therefore, a person skilled in the art, reading Goldberg et al., would find no incentive to prepare chewing gum with a low

moisture content made from biodegradable polymers. The problem that the biodegradable polymers comprised in the chewing gum may hydrolyze (degrade by the action of water) prior to being chewed due to the inherent water-content of the chewing gum is not even addressed in Goldberg et al.

Therefore, the disclosure of Goldberg et al. does not teach, suggest or motivate one skilled the art to obtain a biodegradable chewing gum having a water content of from about 0.01 to about 2.0 weight percent and still expect that it possesses the same desired texture qualities of a traditional, non-biodegradable chewing gum. If anything, Goldberg et al. teaches away from low moisture (water) content chewing gums, since polymers having a higher water uptake ability are favored over those having less water uptake ability.

Accordingly, the rejection of claims 1-30, 32-42, 46, 47 and 49-55 under 35 U.S.C. §103(a) should be reversed and these claims should be allowed in their current form.

D. Claim 31 is improperly rejected under 35 U.S.C §103(a) over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42) and further in view of Grijpma et al. (col. 3, line 4) or Li et al (US 6,153,231, col. 7, lines 60-61).

The rejection of claim 31, which depends from claim 1, is flawed because there is no teaching, suggestion or motivation in Goldberg et al., Grijpma et al, or Li et al. to formulate a biodegradable chewing gum with low water content or to add any type of medicinally active substance to such a formulation.

In addition to the previous arguments, it is noted that Li et al. is directed to "environmentally friendly" chewing gum bases, and resultant chewing gums. The chewing gum base comprises approximately 3 to about 99% by weight poly(lactic acid) copolymers selected

from the group consisting of poly(lactic acid-dimer-fatty acid-oxazoline) copolymers and poly(lactic acid-diurethane) copolymers. There is no teaching or suggestion in Li et al. regarding the water content necessary in the "environmentally friendly" chewing gum so that it possesses the same desirable texture and tactile characteristics as non-biodegradable gum. Li et al. merely discloses and claims that the chewing gum comprise a water soluble portion and a water insoluble base.

Therefore, the rejection of claims 31 under 35 U.S.C. §103(a) should be reversed and these claims should be allowed in their current form.

E. Claims 43-45 and 48 are improperly rejected under 35 U.S.C. §103(a) over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42) and further in view of Meyers (US 5,433,960 cols. 3 and 9-13 and claims 1, 16, 27)

The rejection of the above claims, all of which depend from claim 1, are flawed for at least the reasons given in paragraph C. In addition, as with Goldberg et al., Meyers provides no guidance to one skilled in the art as to how much water is needed for a biodegradable chewing gum to have the desired and comparable texture of a non-biodegradable gum and also how to avoid potential premature degradation of the product. There is no teaching, suggestion or motivation in these combined references to have a biodegradable chewing gum with a water content of from about 0.01 to about 2.0 weight percent and still expect that it will possess the same desired texture qualities of a traditional, non-biodegradable chewing gum.

For at least these reasons, the outstanding rejection of claims 43-45 and 48 under 35 U.S.C. §103(a) is improper and may not be maintained; reconsideration and reversal thereof is respectfully requested.

F. The Office's "Response to Arguments" in the Final Rejection is erroneous

The Examiner's response and arguments in the Final Rejection are erroneous and inconsistent with earlier statements made in the prior rejection. In the final rejection, the Examiner stated that:

Applicant's arguments filed May 21, 2008 have been fully considered but they are not persuasive. Applicant's claimed water content is merely an obvious matter of choice depending upon desired results, personal preference and consumer appeal and in the absence of unexpected results, via a comparison between applicant's claimed water content and the water content disclosed in each primary reference which is closest to that claimed by applicant, can be accorded no patentable weight.

In this Final Office Action, the Examiner failed to consider the arguments from the applicant for determining teachings of the cited prior art documents. Rather, the Examiner impermissibly used hindsight to determine what is obvious or non-obvious. In the Final Office Action the Examiner stated that water content is merely an obvious matter of choice and can be accorded no patentable weight, whereas in the Advisory Action, the Examiner appears to contradict himself and states that lower water content is expected to result in better or longer shelf life. Again, this stated expectancy is not based on prior art but on hindsight from the Examiner.

Having already argued for non-obviousness of the claims on the basis of the cited prior art and with no substantiative rebuttal provided by the Examiner based on the prior art, on 4

December 2008, a response was filed by the Applicant addressing the individual parts of this assertion from the examiner. In response to the Examiner's assertion that "[a]pplicant's claimed water content is merely an obvious matter of choice depending upon: (i) desired results; (ii) personal preference; (iii) consumer appeal; and (iv) in the absence of unexpected results, via a comparison between the Applicant's claimed water content and the (v) water content disclosed in each primary reference which is closest to the amount claimed by the applicant, can be accorded no patentable weight" the Applicants addressed each of these points in the 04 December 2008 response:

i) Desired Results:

Grijpma et al. is directed to a chewing gum comprising certain degradable polymers (see claims 1-8 of Grijpma et al.). Goldberg et al. is directed to a gum base comprising certain degradable polymers (claim 1-16 of Goldberg et al.). In particular, claim 15 of Goldberg et al. claims a desired higher water content. In order to obtain a "desired result," i.e., a biodegradable chewing gum or gum base, one should, according to Grijpma et al. and Goldberg et al., use certain degradable polymers. Accordingly, if a person skilled in the art wants to prepare a degradable chewing gum and looks to either Grijpma et al. or Goldberg et al., s/he would consider polymer content and *not* water content of the chewing gum, as both Grijpma et al. or Goldberg et al. are silent as to critical water content for the chewing gum and/or gum base.

ii) Personal Preference

The Applicant does not understand what the Examiner intends by use of the term "personal preference." The "personal preferences" of Grijpma et al. and Goldberg et al. are to use certain degradable polymers which are suitable for a gum base and chewing gum. If "personal preference" should relate to a specific water content, it is unclear how one skilled in the art would glean such "personal" information from either Grijpma et al or Goldberg et al. One skilled in the art reading Grijpma et al. would readily understand that water content is arbitrarily governed (much less "chosen") by selection of certain water-containing ingredients. Further, since Goldberg et al. seems to favor a higher water content, it is difficult to envision how one skilled in the art would arrive at the chewing gum defined by claim 1 based on their "personal preference."

iii) Consumer Appeal

According to Grijpma et al. and Goldberg et al., "consumer appeal" relates to chewing gum texture, since the polymers used determine the texture of the chewing gum and Grijpma et al. and Goldberg et al. are directed to the use of specific polymers (see for instance Goldberg et al., p. 2, lines 9-21; and Grijpma et al., col. 2, lines 5-9). It is not clear how a person skilled in the art, based upon Grijpma et al. and Goldberg et al. would arrive at the chewing gum defined by claim 1 of the pending application as one having "consumer appeal."

iv) Absence of unexpected results

The Examiner is impermissibly using hindsight when he asserts that the Applicant's limiting of the pre-chew degradation of the chewing gum polymers by keeping the water content of the chewing gum within a certain range (as in claim 1) and, at the same time, obtaining a desired texture, is not an unexpected result. None of the primary references cited by the Examiner identifies the problem which is identified and solved in the pending application. Present claim 1 emphasizes that small amounts of water are beneficial for the texture of the chewing gum of the present invention, in that it requires that the water content of the chewing gum is within a certain range which constitutes a trade-off between limiting pre-chew degradation and promoting the desired texture.

v) The water content disclosed in each primary reference

The water content per se is not disclosed in any of the primary references and it is therefore not possible to make any specific comparisons, as suggested by the Examiner. Example 13 in the pending application compares a biodegradable chewing gum containing about 1.5% water, by weight, with biodegradable chewing gum containing about 0.5% water, by weight. This comparison shows that the shelf life of the biodegradable chewing gum with the lower water content is significantly better than shelf life of the biodegradable chewing gum with the higher water content. In addition, it has been shown that for certain applications, the degradation rate of the chewing gum having a water content of about 1.5%, by weight, may be acceptable.

Thus, the allowable upper limit for the water content, as recited in claim 1 is 2.0%, by weight.

The Examiner's contention that "finding the optimum amount of water to be included in the chewing gum would require nothing more than routine experimentation by one reasonably skilled in the art" is clearly based on hindsight, since the problem solved in the pending application is not even disclosed or suggested to be a potential problem by Grijpma et al., Goldberg et al, Meyers and/or Li et al. Accordingly, claim 1 is not obvious in view of Grijpma et al., Goldberg et al, Meyers and/or Li et al.

- G. Claims 1-55 are improperly rejected under obviousness-type double patenting rejections
1. Claims 1-55 are improperly rejected over claims 1-62 of co-pending US application 10/472,122
 2. Claims 1-55 are improperly rejected over claims 1-54 of co-pending US application 10/472,154
 3. Claims 1-55 are improperly rejected over claims 1-67 of co-pending US application 10/528,926
 4. Claims 1-55 are improperly rejected over claims 1-64 of co-pending US application 10/528,930
 5. Claims 1-55 are improperly rejected over claims 1-57 of co-pending US application 10/528,927
 6. Claims 1-55 are improperly rejected over claims 1-20, 22-26 and 28-42 of co-pending US application 10/529,133
 7. Claims 1-55 are improperly rejected over claims 1, 2, 10, 11, 13-18 24-26, and 28-54 of co-pending US application 11/088,109

The applicants do not agree with the examiners double patenting rejections. However, Applicants are **not** appealing these rejections, and in order to further the prosecution of the case, applicants will sign the appropriate terminal disclaimers, once allowable subject matter has been defined.

In summary and in light of the foregoing, Applicants request that the pending rejection be reversed, and that the pending claims be allowed in their present form.

H. Missing Abstract

Finally, the Applicants note that in the February 25, 2008 Office Action, the Examiner states that this application does not contain an abstract of the disclosure, as required by 37 CFR 1.72(b). In response to this request, the Applicants will submit an abstract once allowable subject matter has been defined. Again, this issue is **not** being appealed.

Respectfully submitted,

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April 2, 2009

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VIII. Claims Appendix

1. Chewing gum comprising at least one biodegradable polymer and chewing gum ingredients, wherein said chewing gum ingredients are selected from the group consisting of softeners, sweeteners, flavoring agents, active ingredients, fillers, and mixtures thereof; and wherein said chewing gum contains from about 0.01 to about 2.0 weight percent water by weight of the chewing gum.
2. (Canceled)
3. Chewing gum according to claim 1, wherein said chewing gum contains less than 1.0 weight percent water by weight of the chewing gum.
4. Chewing gum according to claim 1, wherein said chewing gum contains less than 0.75 weight percent water by weight of the chewing gum.
5. Chewing gum according to claim 1, wherein said chewing gum contains less than 0.2 weight percent water by weight of the chewing gum.
6. Chewing gum according to claim 1, wherein at least one biodegradable polymer is a polyester polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters is selected from the group consisting of glycolides, lactides, lactones, cyclic carbonates and mixtures thereof.

7. Chewing gum according to claim 1, wherein the at least one biodegradable polymer is a polyester copolymer obtained by the polymerization of two or more cyclic esters by ring-opening and where at least one of the cyclic esters is selected from the group consisting of glycolides, lactides, lactones, cyclic carbonates and mixtures thereof.

8. (Cancelled)

9. Chewing gum according to claim 1, wherein the lactones are chosen from the group consisting of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, β -propiolactone, and mixtures thereof; and wherein the lactones are optionally substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atom along the ring, including compounds in which two substituents are contained on the same carbon atom.

10. Chewing gum according to claim 7, wherein the cyclic carbonate is selected from the group consisting of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4,6-dimethyl-1,3-propylene carbonate, 2,2-dimethyl trimethylene carbonate, 1,3-dioxepan-2-one and mixtures thereof.

11. Chewing gum according to claim 1, wherein the chewing gum is substantially free of water containing sweeteners or softeners.

12. Chewing gum according to claim 1, wherein the chewing gum comprises at least one low hygroscopic softener or sweetener.
13. Chewing gum according to claim 12, wherein the at least one low hygroscopic softeners or sweetener comprises powdered erythritol.
14. Chewing gum according to claim 1, wherein said chewing gum ingredients comprise flavoring agents.
15. Chewing gum according to claim 14, wherein said flavoring agents comprise natural and synthetic flavorings in the form of natural vegetable components, essential oils, essences, extracts, powders, including acids.
16. Chewing gum according to claim 14, wherein said chewing gum comprises flavoring agents in an amount of 0.01 to about 30 wt %, said percentage being based on the total weight of the chewing gum.
17. Chewing gum according to claim 14, wherein said chewing gum comprises flavoring agents in an amount of 0.2 to about 4 wt %, said percentage being based on the total weight of the chewing gum.

18. Chewing gum according to claim 14, wherein said flavoring agents comprise water soluble ingredients.
19. Chewing gum according to claim 18, wherein said water soluble ingredients comprise acids.
20. Chewing gum according to claim 14, wherein said flavoring agents comprise water insoluble ingredients.
21. Chewing gum according to claim 1, wherein said chewing gum ingredients comprise sweeteners.
22. Chewing gum according to claim 21, wherein said sweeteners comprise bulk sweeteners.
23. Chewing gum according to claim 22, wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to about 95% by weight of the chewing gum.
24. Chewing gum according to claim 21, wherein said sweeteners comprise high intensity sweeteners.
25. Chewing gum according to claim 24, wherein the high intensity sweeteners comprise sucralose, aspartame, salts of acefulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, steryioside, alone or in combination.

26. Chewing gum according to claim 24, wherein the chewing gum comprises high intensity sweeteners in an amount of about 0 to about 1% by weight of the chewing gum.
27. Chewing gum according to claim 1, wherein the chewing gum comprises at least one softener.
28. Chewing gum according to claim 27, wherein the at least one softener comprises tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids, stearic acid, palmitic acid, oleic acid, linoleic acid, waxes, poly glycol esters or mixtures thereof.
29. Chewing gum according to claim 27, wherein the chewing gum comprises softeners in the amount of about 0 to about 18% by weight of the chewing gum.
30. Chewing gum according to claim 1, wherein said chewing gum ingredients comprise active ingredients.
31. Chewing gum according to claim 30, said active ingredients selected from the group consisting of Acetaminophen, Acetylsalicylic acid, Buprenorphine, Bromhexin, Celcoxib, Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Rofecoxib, Tenoxicam,

Tramadol, Valdecocixib, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron, Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, Ieco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium, Haloperidol, Allopurinol, Colchicine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorphin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetirizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine, Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphthalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetone, Melatonin, Phenobarbital, Caffeine, Benzodiazepine, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamine, Pseudoephedrine, Sibutramine, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetate, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesium oxide, Nizatide and Ratinidine and mixtures thereof.

32. Chewing gum according to claim 1, wherein the chewing gum is substantially free of non-biodegradable polymers.
33. Chewing gum according to claim 32, wherein the least one biodegradable polymer is a polyester polymer obtained by the polymerization of at least two or more cyclic esters selected from the group consisting of glycolides, lactides, lactones, cyclic carbonates and mixtures thereof.
34. Chewing gum according to claims 33, wherein said lactones are chosen from the group consisting of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, β -propiolactone and mixtures thereof; and wherein the lactones are optionally substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atom along the ring, including compounds in which two substituents are contained on the same carbon atom.
35. Chewing gum according to claim 33, wherein the cyclic carbonate is selected from the group consisting of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4,6-dimethyl-1,3-propylene carbonate, 2,2-dimethyl trimethylene carbonate, 1,3-dioxepan-2-one and mixtures thereof.
36. Chewing gum according to claim 6, wherein the polyester polymer is selected from the group consisting of: poly (L-lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ;

poly (glycolide) ; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone); poly (L-lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L-lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ; poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co-glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso-lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly (glycolide-co-epsilon-caprolactone); and mixtures thereof.

37. Chewing gum according to claim 1, wherein the chewing gum comprises filler.
38. Chewing gum according to claim 37, wherein the chewing gum comprises filler in an amount of about 0 to about 50% by weight of the chewing gum.
39. Chewing gum according to claim 1, wherein the chewing gum comprises at least one coloring agent.
40. Chewing gum according to claim 1, wherein the chewing gum is coated with an outer coating.
41. Chewing gum according to claim 40, wherein the outer coating is a hard coating.

42. Chewing gum according to claim 41, wherein the hard coating is a coating selected from the group consisting of a sugar coating and a sugarless coating and a combination thereof.

43. Chewing gum according to claim 41, wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol, isomalt, and mixtures thereof.

44. Chewing gum according to claim 40, wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

45. Chewing gum according to claim 44, wherein the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatin, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

46. Chewing gum according to claim 40, wherein the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavoring agent, a coloring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar and an acid.

47. Chewing gum according to claim 40, wherein the outer coating is a soft coating.

48. Chewing gum according to claim 47, wherein the soft coating comprises a sugar free coating agent.
49. Chewing gum according to claim 1, wherein said chewing gum comprises conventional chewing gum polymers or resins.
50. Chewing gum according to claim 1, wherein the at least one biodegradable polymer comprises at least 5% of the chewing gum polymers.
51. Chewing gum according to claim 1, wherein all the biodegradable polymers comprised in the chewing gum comprise at least 25% of the chewing gum polymers.
52. Chewing gum according to claim 1, wherein all the biodegradable polymers comprised in the chewing gum comprise at least 80% of the chewing gum polymers.
53. Chewing gum according to claim 1, wherein said chewing gum comprises
- at least one biodegradable polyester copolymer forming a plasticizer of the chewing gum and
 - at least one non-biodegradable conventional elastomer.
54. Chewing gum according to claim 1, wherein said chewing gum comprises
- said at least one biodegradable polyester copolymer forming an elastomer of the chewing gum and

- at least one non-biodegradable conventional natural or synthetic resin.

55. Chewing gum according to claim 1, wherein said chewing gum comprises at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum, at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and at least one chewing gum ingredient chosen from the group consisting of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

IX. EVIDENCE APPENDIX

None.

X. Related Proceedings Appendix

None.